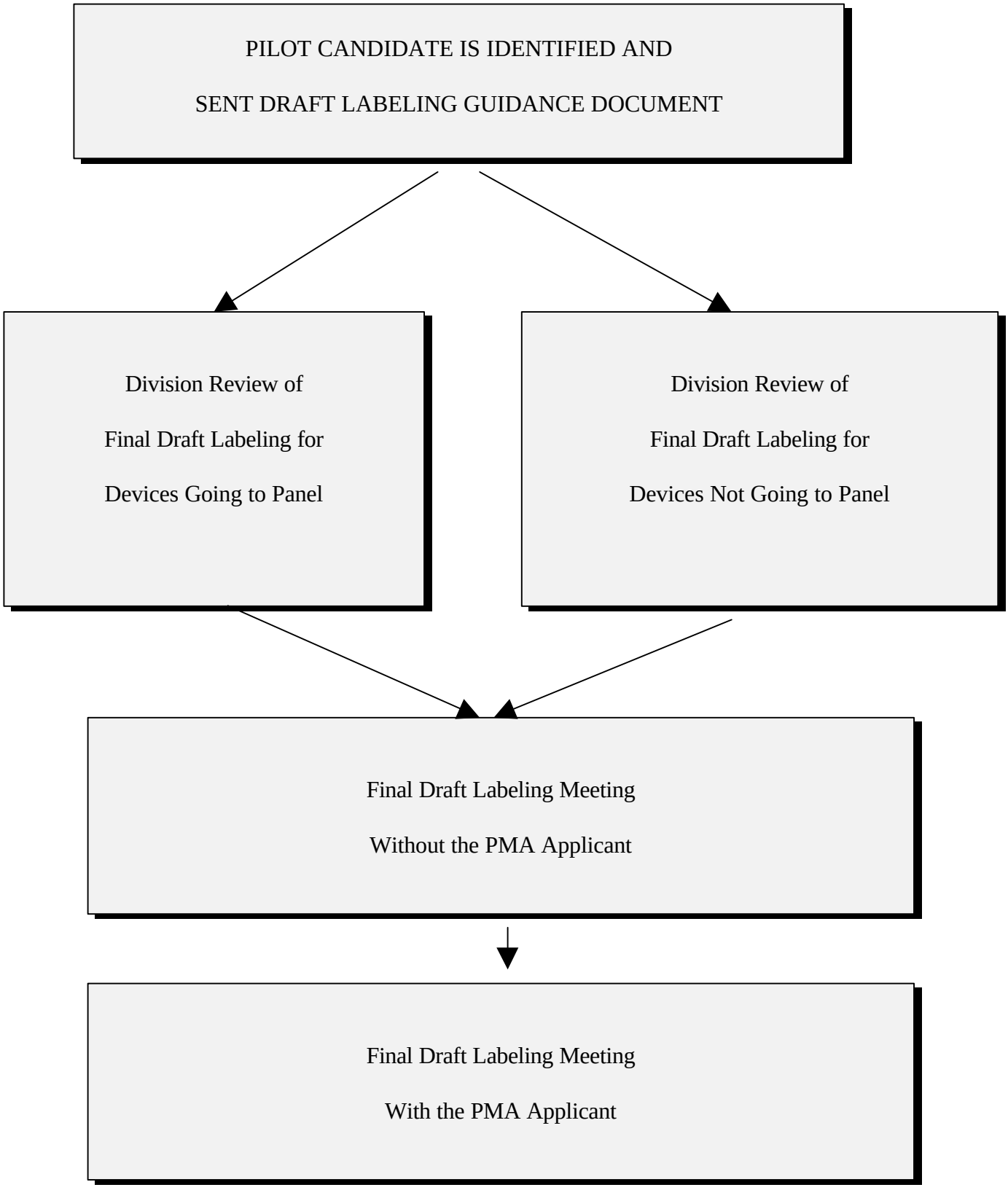
Date: October 29, 1997

Labeling Closure

The PMA reengineering team has recommended an interactive review of final draft labeling including the applicant, ODE division and office staff, OST reviewers, OSB Division of Biostatistics reviewers and OHIP staff to help reach closure on labeling more efficiently. ODE management is in agreement with this assessment.

We are initiating a pilot for interactive review of final draft labeling. The provided method (attached) addresses many of the problems with the current process. However, we also recognize that some circumstances, such as type of device, previous experience with the device type, and company experience, may modify the way you use the pilot process.

ODE division directors or their deputies/associates have responsibility for ensuring an interactive final draft labeling review meeting with the applicant under this pilot. They also have the discretion to modify the attached process to meet the needs of the particular submission.


PILOT CANDIDATE IS IDENTIFIED AND
SENT DRAFT LABELING GUIDANCE DOCUMENT
Division Review of
Final Draft Labeling for
Devices Going to Panel
Division Review of
Final Draft Labeling for
Devices Not Going to Panel
Final Draft Labeling Meeting
Without the PMA Applicant
Final Draft Labeling Meeting
With the PMA Applicant

Identify PMA Candidates for Pilot.
Send the PMA Applicant Candidate:

1. A cover letter requesting the applicant consider participating in the pilot.
   and
2. The draft guidance document entitled "Medical Device Labeling - Suggested Format and Content."

Division Review of Final Draft Labeling for Devices Going to Panel

Division review should be completed within sufficient time to:

1. Provide draft labeling to the Panel;
2. develop Panel labeling questions; and
3. brief the ODE Director prior to the Panel meeting.

Division should work with PMA applicant to resolve as many outstanding labeling issues as possible prior to the Panel meeting

Division Review of Final Draft Labeling for Devices Not Going to Panel

Division review should be completed concurrently with the scientific review.

Specific detailed deficiencies regarding labeling should be communicated to PMA applicant.

Division should schedule a meeting with ODE Director regarding final draft labeling

Final Draft Labeling Meeting Without the PMA Applicant

This meeting should be held within 5 working days of the date:

1. of the response to an approvable letter identifying labeling concerns;
2. an approvable letter is issued which did not identify any labeling concerns; or
3. of FDA's determination that there are no remaining deficiencies.

For PMAs under review prior to the date of enactment of the FDA Modernization Act of 1997, this meeting should be held within 10 working days following the issuance of either:

1. a not approvable letter; or
2. a major deficiency letter that does not affect final draft labeling.

Following this meeting, the division should contact the PMA applicant to discuss FDA's recent labeling review. PMA applicant should be asked to provide FDA with feedback, i.e., points of disagreement and/or concurrence with FDA's findings.

Final Draft Labeling Meeting With the PMA Applicant

To be held within 10 working days of the Final Draft Labeling Meeting Without the PMA Applicant.

Meeting participants, including the ODE Director, discuss and agree on the final draft labeling, i.e., package labels, package inserts, technique manuals, and patient labeling, for the device.

Pilot for Review of Final Draft Labeling
by FDA and PMA Applicants

Introduction:

The goal of the Pilot for Review of Final Draft Labeling is to efficiently facilitate early agreement between FDA and the PMA applicant on the final labeling for PMA products.

Pilot Description:

The pilot establishes a new procedure for interactive final draft labeling review meetings. For those PMAs and panel tracked supplements, not to exceed 3 per division, due by January 31, 1998, for which the division has not yet finalized the labeling, and for which the division has determined that the PMA applicant will benefit from this type of interactive review, a meeting will be held between relevant FDA and PMA stakeholders to finalize the labeling of the PMA device. The meeting may be face-to-face, or may take place via a conference call utilizing a fax machine or video conferencing.

Procedures, Roles and Responsibilities:

Each ODE Division should send a letter to all potential pilot PMA applicants asking if they would like to participate in the pilot. A copy of the draft guidance document "Medical Device Labeling - Suggested Format and Content" should be enclosed with the letter. A copy of the boilerplate letter is attached to this document and also can be located in the H: drive (H:/PMA pilot review of final draft labeling).

The following are the suggested steps for the pilot:

1. Division Review of Final Draft Labeling

a. PMAs Going to Panel

For the pilot PMAs going to Panel, division review of the label should be completed in sufficient time to: (i) provide draft labeling to the Panel; (ii) develop Panel labeling questions; and (iii) brief the ODE director prior to the Panel meeting. POS should be invited to such briefings. The purpose of the pre-panel review is to critique and modify the working drafts of the labeling, as needed. The division should work with the PMA applicant to resolve as many outstanding labeling issues as possible prior to the Panel meeting.

Working drafts of the labeling, which may include labeling issues that could not be resolved prior to the Panel meeting, should be sent to the Panel as part of FDA's background materials for the PMA. The drafts will also be sent to the applicant with an explanation that these are the current working drafts, but are likely to be affected by the Panel's discussion of the PMA and additional internal review of outstanding issues.

b. PMAs Not Going to Panel

For the pilot PMAs not going to Panel, division review of labeling should be completed concurrent with the scientific review. Specific detailed deficiencies regarding labeling should be communicated to the PMA applicant as early as possible, in an interactive format.

Following this review, the division should schedule a briefing with the ODE director regarding the final draft labeling. POS should be included in such briefings.

2. Final Draft Labeling Meeting Without the PMA Applicant

The Review Team (Lead Reviewer, Branch Chief, Medical Officer, Division Director, PMA staff, ODE Director, Statistician, OHIP representative, and ODE Director as necessary) will meet to develop a final working draft that will be shared with the applicant. The team leader will provide the meeting participants with a draft of the final labeling *at least 1 day* before the meeting.

The purpose of this meeting is to:
a. incorporate the Panel's comments, if applicable;
b. review any new information learned about the PMA device;
c. critique the latest version of the labeling; and
d. make any necessary modifications to the labeling.

Depending on the particular PMA, the Final Draft Labeling Meeting Without the PMA Applicant should be completed *within 5 working days* of the date:
a. of the response to the Approvable letter;
b. the Approvable letter is issued; or
c. of FDA's determination that there are no remaining deficiencies.

For PMAs under review prior to the date of enactment of the FDA Modernization Act of 1997, the Final Draft Labeling Meeting Without the PMA Applicant should be completed *within 10 working days* following the issuance of a not approvable or major deficiency letter which does not effect final draft labeling.

Immediately after this internal meeting, the PMA applicant will be contacted to discuss FDA's recent review and to schedule the Final Draft Labeling Meeting with the PMA Applicant (see number 3 below). The PMA applicant is to be notified of FDA's most recent review of his/her labeling in sufficient time for the PMA applicant to respond to FDA's issues.

The PMA applicant should be asked to identify any areas of disagreement for discussion at the Final Draft Labeling Meeting With the PMA Applicant.

After receiving feedback from the PMA applicant, the division should circulate to team members, and ODE management as necessary, the points of disagreement between the applicant and FDA. If an internal meeting is determined to be necessary to discuss these points, the division should schedule a meeting prior to the Final Draft Labeling Meeting With the PMA Applicant.

3. Final Draft Labeling Meeting with the PMA Applicant

This meeting should be held within *10 working days* from the Final Draft Labeling Meeting without the PMA Applicant. Participants include the Lead Reviewer, Branch Chief, Medical Officer, Division Director, PMA Staff, ODE Director, Statistician, OHIP Representative and the PMA applicant. The team leader will provide the review team members with the relevant materials 48 hours prior to this meeting.

The purpose of this meeting is to discuss and agree on the final draft labeling (i.e., package labels, package insert, technique manuals, patient labeling) for the device.

Note: This meeting is likely to be 3-5 hours in duration. Some members of the review team may participate in only a portion of the meeting (e.g. OHIP may only be present during patient labeling review).

Measures:

In order to assess whether the final draft labeling meeting procedure is effective the following should be completed:

1. Each division should identify one individual to be responsible to track the time elapsed from division review of final draft label to final draft labeling meeting with the PMA applicant.
2. Critique of the process at the final draft labeling meeting with the PMA applicant. Both FDA and the PMA applicant will provide verbal feedback about the pilot.

CDRH Program Areas Affected:

ODE (All divisions, PMA staff, Office Director)
OSB
OST (reviewers)
OHIP